REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claim Amendments

Claims 4-7 have been amended to delete the phrase "or a pharmacologically acceptable salt thereof".

Independent claim 9 has been added to recite a method for treating a skin wound and for alleviating pain associated with the skin wound as in claim 4, "and wherein the medicine does not retard wound-healing." Support for such amendment can be on page 3, line 16 of the specification.

Rejection Under 35 U.S.C. § 112, First Paragraph

The rejection of claims 6 and 7 under 35 U.S.C. §112, first paragraph, is respectfully traversed.

The specification discloses many examples in which Aspirin is within the concentration ranges of 0.5 to 20% or 5 to 20%. See Examples 1-14.

MPEP 2163.05(III) sets forth that "[with] respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure." Moreover, in the decision of *In re Wertheim* (191 USPQ 90 (CCPA, 1976)), cited by the MPEP, the court held that a limitation of "between 35% and 60%" met the description requirement even though the original specification set forth only a range of "25% to 60%" and **specific examples** of "36%" and "50%", emphasis added. Page 4 of the present specification discloses that acetylsalicylic acid contained in the external preparations is from "0.01 to 80%". However, the examples disclose acetylsalicylic acid concentrations of up to 20%, as the Examiner acknowledges. Accordingly, based on MPEP 2163.05(III) and *In re Wertheim*, a person having ordinary skill in the art would clearly consider the recited ranges of claims 6 and 7 to be at least inherently supported by the original disclosure.

Thus, contrary to the Examiner's position that claims 6 and 7 contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art…", a person having ordinary skill in the art would consider the ranges recited in claims 6 and 7 as fully supported by the disclosure including examples.

Furthermore, the phrase "a pharmaceutically acceptable salt" has been deleted from the claims.

Therefore, the rejection of claims 6 and 7 under 35 U.S.C. §112, first paragraph, should be withdrawn.

Rejection Under 35 U.S.C. § 103(a)

The patentability of the present invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Thus, the rejection of claims 4-7 under 35 U.S.C. §103(a) as being unpatentable over Inamoto et al. (US 2003/0125308, as the English equivalent of WO 2001/047525, hereinafter "Inamoto") as evidenced by Reller (US 4,219,548) and further in view of Baxter (Nursing Times, Vol. 99, No. 13, 2003, pages 1-5), is respectfully traversed.

Inamoto

As argued heretofore, Inamoto relates to an external preparation having excellent antipruritic activity containing acetylsalicylic acid (Aspirin) as an active ingredient.

However, Inamoto fails to disclose that acetylsalicylic acid is useful for treating a skin wound selected from the group consisting of infectious disease in surgery, and vessel and lymphangiopathy, without retarding the healing of the wound, or for alleviating pain associated with such skin disease, by the application of the preparation to an affected area on the patient.

Therefore, the present invention in claims 4-7 is not suggested by Inamoto.

Combination of Reller and Inamoto

Reller discloses that Aspirin is useful for the treatment of inflammation of skin, including dermatoses accompanied by inflammation, skin injury, contact burns and insect bites, by topical

administration. Example II of Reller teaches that topical administration of Aspirin is useful in reducing inflammation and the sensation of itching and pain.

However, Reller fails to disclose that Aspirin is useful for treating a skin wound selected from the group consisting of infectious disease in surgery, and vessel and lymphangiopathy, without retarding the healing of the wound, or for alleviating pain associated with such skin disease, by the application of Aspirin to an affected area on the patient.

Thus, Inamoto and Reller both fail to suggest that Aspirin is useful for treating a skin wound selected from the group consisting of infectious disease in surgery, and vessel and lymphangiopathy, without retarding the healing of the wound, and for alleviating pain associated with such skin disease, by its application to an affected part of a patient.

Therefore, it would not have been obvious for a skilled person in the art to arrive at the subject matter of claims 4-7 from the disclosures of Inamoto in combination with Reller.

Combination of Baxter with Inamoto and Reller

Baxter discloses that a potential surgical complication is infection. Infections due to surgical wound complications and characteristic properties of wound infections are also described therein. However, Baxter fails to suggest that Aspirin is useful for treating such wound infections.

Thus, the present invention would not have been obvious to a person having ordinary skill in the art since none of the references suggest treating a skin wound selected from the group consisting of infectious disease in surgery, and vessel and lymphangiopathy with Aspirin, without retarding the healing of the wound, and for alleviating pain associated with such skin disease.

Unexpected Results

Moreover, a person having ordinary skill in the art would not attempt to use Aspirin to treat skin wounds selected from the group consisting of infectious disease in surgery, and vessel and lymphangiopathy, because it is known in the art that medicating a wound with a nonsteroidal anti-inflammatory agent **actually inhibits wound healing**. Specifically, page 2, lines 2-4 of the present specification explains that "[m]oreover, generally, since medication to wound region of a

nonsteroidal anti-inflammatory agent **retards wound-healing**, such medication in the wound region is considered to be contraindication", emphasis added.

As shown in Table 9 on page 17 of the specification, in the case where a nonsteroidal anti-inflammatory agent, indomethacin (Comparative Example 1) was applied to a wound region (deficit area), the wound actually worsened when compared with treatment with ointments of the present invention containing Aspirin (Examples 1, 5, 10 and 11). Thus, it is recognized that application of indomethacin to the wound region retards wound-healing.

On the other hand, in the case that the specific nonsteroidal anti-inflammatory agent, Aspirin, was applied to the wound region (Examples 1, 5, 10 and 11), its effect was nearly equal to or superior to the effects of conventional commercial wound-healing agents (Comparative Examples 2 and 3), but Aspirin does not retard wound-healing.

Thus, a skilled person in the art would recognize from the present application that there are unexpected and superior results of Aspirin over other well-known nonsteroidal anti-inflammatory agents, such as indomethacin. Such unexpected results of the presently claimed invention have not been disclosed or suggested in any prior art cited by the Examiner.

Also, based on the above, it is clear that a person having ordinary skill in the art would not have combined the teachings of Inamoto, Reller and Baxter in the first place, since it would have been expected that treating a wound with Aspirin would actually inhibit the healing of the wound.

Accordingly, the present invention is non-obvious over the prior art cited by the Examiner and this rejection should be withdrawn.

Conclusion

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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